



May 18, 1999

Food and Drug Administration  
5630 Fishers Lane, room 1061  
Rockville, Md., 20852

To whom it may concern,

Accompanying this letter are our comments regarding docket no. 98N-1038, "Irradiation in the Production, Processing, and Handling of Food," which we attempted to send by fax on May 18<sup>th</sup>. The receiving fax rang continuously without answering, preventing us from transmitting our comments. Therefore, I am instead now FedExing them to you, trusting that they will still be given fair and equal consideration. If this is not the case, or if you have any questions, please contact me at (301) 258-3056. Thank you very much.

Most sincerely,

*Mary Finelli*

Mary Finelli  
Senior Researcher  
Farm Animals and Sustainable Agriculture



The Humane Society  
of the United States

Mary Finelli  
Senior Researcher  
Farm Animals and  
Sustainable Agriculture

301-258-3056  
Fax: 301-258-3081

The Humane Society of the United States  
2100 L Street, NW, Washington, DC 20037  
202-452-1100 • Fax: 202-778-6132 • Internet: www.hsus.org

98N-1038

C2409



#### OFFICERS

Joe Ramsey, Esq.  
*Chairman of the Board*  
David O. Wiebers, M.D.  
*Vice Chairman*  
Amy Freeman Lee, Litt.D.  
*Secretary*  
Paul G. Irwin  
*President, CEO*  
G. Thomas Waite III  
*Treasurer, CFO*  
Patricia A. Forkan  
*Executive Vice President*  
Roger A. Kindler, Esq.  
*Vice President/General Counsel*

#### STAFF VICE PRESIDENTS

John W. Grandy, Ph.D.  
*Senior Vice President  
Wildlife Programs*  
Wayne Pacelle  
*Senior Vice President  
Communications and  
Government Affairs*  
Andrew N. Rowan, Ph.D.  
*Senior Vice President  
Research, Education, and  
International Issues*  
Melanie Adcock, D.V.M.  
*Farm Animals and  
Sustainable Agriculture*  
Martha C. Armstrong  
*Companion Animals and  
Equine Protection*  
Katherine Benedict  
*Information Management Systems*  
Richard M. Clugston, Ph.D.  
*Higher Education*  
Randall Lockwood, Ph.D.  
*Training Initiatives*  
Deborah J. Salem  
*Publications*  
Martin L. Stephens, Ph.D.  
*Animal Research Issues*  
Richard W. Swain Jr.  
*Investigative Services*  
Carroll S. Thrift  
*Business Development and  
Corporate Relations*

#### DIRECTORS

Peter A. Bander  
Donald W. Cashen, Ph.D.  
Anita W. Coupe, Esq.  
Judi Friedman  
Alice R. Garey  
Denis A. Hayes, Esq.  
Jennifer Leaning, M.D.  
Amy Freeman Lee, Litt.D.  
Eugene W. Lorenz  
Jack W. Lydman  
William F. Marcuso  
Joan C. Martin-Brown  
Judy J. Peil  
Joe Ramsey, Esq.  
Jeffery O. Rose  
James D. Ross, Esq.  
Marilyn G. Seyler  
John E. Taft  
Robert F. Welborn, Esq.  
David O. Wiebers, M.D.  
Marilyn E. Wilhelm  
K. William Wiseman  
John A. Hoyt  
*President Emeritus*  
Murdaugh Stuart Madden, Esq.  
*Vice President/Senior Counsel*  
Printed on recycled paper

Irradiation in the Production, Processing, and Handling of Food

Docket No. 98N-1038

21 CFR Part 179

Advanced Notice of Proposed Rulemaking

Department of Health and Human Services

Food and Drug Administration

May 18, 1999

Comments of The Humane Society of the United States

The Humane Society of the United States  
2100 L Street, NW, Washington, DC 20037  
202-452-1100 • Fax: 202-778-6132 • Internet: [www.hsus.org](http://www.hsus.org)

The Humane Society of the United States (HSUS), on behalf of its more than seven million members and constituents, appreciates this opportunity to respond to the Food and Drug Administration (FDA)'s advance notice of proposed rulemaking, "Irradiation in the Production, Processing, and Handling of Food" [Docket No. 98N-1038]. Currently, FDA regulations require that retail packages or displays of foods treated with ionizing radiation include a disclosure statement (either "Treated with radiation," or "Treated by irradiation") prominently and conspicuously accompanied by the radura, the international symbol of irradiation. This notice pertains to changes to these regulations which the FDA is presently considering. The HSUS responds to the agency's request for input, namely on: (1) Whether the wording of the current radiation disclosure statement should be revised and (2) whether such labeling requirements should expire at a specified date in the future, by presenting the following explanation of our reasons for opposing both changes.

#### Disclosure of a Material Fact of Great Concern to the Public

Undeniably, the current radiation disclosure statement is informational. How this information is perceived by consumers will, of course, vary with each individual. The more than 5,000 comments which the FDA received back in 1984 in response to its notice on food irradiation -which ultimately led to the agency's 1986 final rule requiring the labeling of retail packages and displays of irradiated food to bear both a radiation disclosure statement and the radura- attest to the level of public concern about food irradiation. Clearly the information conveyed in the radiation disclosure statement is very meaningful and important to the public.

The FDA previously determined that irradiation is a form of processing that can produce significant changes in certain characteristics of a food, such as the organoleptic (e.g., taste, smell, texture) or holding properties, in a manner that is not obvious to the consumer in the absence of labeling. It concluded that labeling of irradiated foods is necessary because such processing is a material fact that must be disclosed to the consumer to prevent deception. This material fact holds true today. Though it might be apparent that a food product has been processed, this is not the case for food products (or ingredients) processed by irradiation. They must be prominently and conspicuously labeled as such in order to prevent the public from being deceived.

The current disclosure statement is a simple, concise declaration of this material fact in the absence of which consumers would have no way of ascertaining this important information. The current required statement conveys this information to consumers in a truthful manner which in no arguable way can be considered misleading. The statement, prominent and conspicuously displayed with a radura, is a very valid and effective way to convey this important information to consumers, including those who may not be able to read English.

## Irradiation Hazards

The current radiation disclosure statement does not cause “inappropriate anxiety” among consumers. There are grave and valid concerns about the safety of irradiated food. The intuitive concerns of consumers who are unfamiliar with the facts involving food irradiation may very well be justifiable ones. No long term studies of the human health effects of consuming irradiated food have been conducted. Molecular changes occur in irradiated food which are potentially hazardous. For example, higher levels of carcinogenic benzene may result. Irradiated food contains unique chemical compounds that have never been tested for toxicity. Tell-tale “indicator” organisms, which are harmless but give off odors and other signals indicating that food has gone bad, are killed by irradiation. Many pathogenic organisms are undetectable, and new or surviving ones may multiply to dangerous levels in irradiated food, endangering consumers. There are also other serious human safety and environmental concerns about food irradiation which have not been adequately addressed.

A substantial portion, possibly a majority, of the population hold strong feelings on food irradiation for a variety of reasons (e.g., health, environmental, sociological, etc.), and want to be able to identify food which has been irradiated. They should have the ability to readily do so. It is the lack of a candid radiation disclosure statement, such as the current one, which would cause consumers inappropriate anxiety in that they would no longer be able to differentiate between irradiated and nonirradiated foods and have the freedom of choice to knowingly avoid or consume them.

## Prominent, Conspicuous and Truthful Labeling

Since most food has as yet not been irradiated, consumers will understandably continue to assume that the food they purchase and consume has not been irradiated unless it is so labeled. Therefore, it would be deceptive not to have a disclosure statement prominently and conspicuously displayed on a food label or other appropriate device. This holds true for food products and multi-ingredient products containing any individual ingredients which have been irradiated. In order for consumers to be able to avoid or purchase and consume the type of products they want, products must be accurately labeled.

Consumers may not readily recognize the radura and associate it with irradiation. Therefore, it is important for irradiated food to also prominently and conspicuously display a radiation disclosure statement. (Allowing this declaratory statement to be no more prominent than the declaration of ingredients, which are, at times, barely apparent, is not sufficient. A more reasonable requirement is for the lettering of said statement to be at least one-third the size of the largest letter in the product name.) If consumers do become familiar with the radura, it will enable them to more readily identify irradiated foods. The radura will also be helpful to those who do not read English. It should therefore also be prominently and conspicuously placed.

To even suggest that irradiated food not be labeled as such is outrageous. The irradiation industry and others who advocate the irradiation of food need to convince the public of its value, not underhandedly impose it on them with absent or obscure labeling which eliminates their ability

to make a free and informed choice. Irradiation is a relatively new, highly controversial and, to many people, a highly objectionable and unnecessary method of processing food. It should not be foisted on the public by concealing the fact or distorting it with the use of euphemisms such as “electronic pasteurization” or “cold pasteurization” - a term which does not even make sense.

Industry’s insinuation that the public is incapable of making an intelligent decision based on clear and factual identification of irradiated food is patently offensive. (We, in fact, take issue with the wording of question four in the notice, which implies that the current disclosure statement wording is “threatening.”) Public rejection of irradiated food may very well be based on valid concerns about the irradiation process and what it entails. Industry should stop attempting to pressure the government into concealing from the public the material fact that a food product or ingredient has been irradiated. If the public interest is the government’s concern, by no means should the government succumb to this. The FDA, being entrusted with the responsibility for the accurate and truthful labeling of irradiated food, needs to require that irradiated food products and ingredients be prominently and conspicuously labeled as such.

#### No Expiration Date for Any Labeling Requirements

Since food irradiation in the United States is essentially a recent development, certainly for meat and poultry, it is at best premature to consider the expiration of any radiation disclosure statement requirements. Once instituted, labeling should prove no hardship for industry (if it ever is). It may, in fact, then prove more of a hardship for industry they were to expire. Irradiation of food will always be a material fact which should be plainly disclosed to the public.

#### The Needlessness of Irradiation

For these reasons, The Humane Society of the United States opposes revising the wording of the current radiation disclosure statement and the expiration of the labeling requirements at any date in the future. Bacterial contamination of meat and meat products is certainly a very serious problem. However, irradiation is not an appropriate or feasible way to address this problem. It is an experimental and potentially dangerous technology which puts the public at unnecessary risk. There are better approaches which have not been adequately attempted or employed.

In its recent irradiation proposal, the Food Safety Inspection Service of the United States Department of Agriculture stated: “the load of pathogens on incoming product can vary widely, due to animal husbandry and sanitation practices.” These husbandry and sanitation practices are not being effectively addressed by industry or government. There are safer, more effective methods of pathogen control that should be employed rather than resorting to irradiation. Irradiation is being looked to as a way to avoid having to address the source of foodborne infectious organisms - the factory “farming” of animals. Irradiation will also do nothing to control pathogens in animal manure used as animal feed or as fertilizer for fruits, vegetables, and other crops which can become contaminated as well. It is an unnecessary, desperate measure of grave concern. Given the significant risks and the needlessness of it, if food irradiation is allowed it should be forced to meet the most stringent of requirements, including labeling requirements.

Align top of FedEx PowerShip Label here.

-8N-1038

MAILROOM  
HUMANE SOCIETY OF THE U.S.  
700 PROFESSIONAL DR  
GAITHERSBURG MD 20879  
(301)258-3089

SHIP DATE: 19MAY99  
ACC# 113535717  
ACTUAL WGT: 1 LBS MAN-WT

TO:  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville MD 20852  
(301)827-6880

4260 6457 2690

**FedEx.**

REF: Mailroom

STANDARD OVERNIGHT THU:

CAD# 0645848 19MAY99

TRK# 4260 6457 2690 Form 0201

Deliver by:

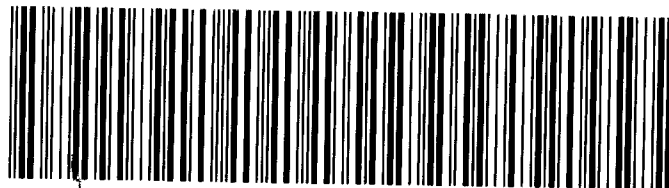
20MAY99

IAD

AA

20852 -MD-US

19 EDGA



*World On Time*